Appendix D

Performance Tests for General Fluoroscopic Units

A. General Performance Tests for Fluoroscopic Equipment

1. ***kVp Accuracy***

a. Purpose: To verify that tube voltage potential accurately tracks the nominal generator setting.

b. Equipment: Exposure rate compatible kVp meter.

c. Procedure:

(1) Follow the meter manufacturer's instructions.

(2) Some meters may have restricted operating ranges or require specific techniques.

(3) Test the unit in manual kVp mode whenever possible. Test units without manual kVp control at the voltage provided by the automatic brightness control (ABC) system for the kVp meter assembly in the beam.

(4) Record average or effective kVp, as available, when using a meter offering multiple reading formats.

d. Interpretation of Results: Refer units deviating from the criteria in Table 4.1 for adjustment by a qualified service engineer. Proper kVp calibration is critical as it directly influences image quality and patient dose.

2. ***Entrance Exposure Rate (EER) Measurements (Typical)***

a. Purpose:

(1) To establish and maintain reasonably low typical exposure rates. JCAHO requires that "typical" fluoroscopic exposure rates be monitored.

(2) To verify long term EER consistency.

(3) To verify proper automatic brightness control of exposure rate with varying image intensifier (II) field size.

b. Equipment: 4 cm Al or 15 cm acrylic phantom, exposure meter & small ion chamber.

c. Procedure:

(1) Refer to the general measurement set up for the tested unit (Figures D-1 and D-2).

(2) Typical and maximum EER measurements can be made with the same basic equipment arrangement.

(3) Place the ion chamber at the location specified by 21 CFR 1020.32(d), (e).

(4) Invert C-arms for testing. This allows for easier phantom placement.

(5) Treat LUA systems as standard/ C-arm hybrids (i.e. meet both conditions).

(6) For adjustable C-arms and LUAs, minimize the focal spot to ion chamber distance.

(7) Place the phantom close to the ion chamber, but far enough away to minimize backscatter to the ion chamber and completely shield the image intensifier. The II is very sensitive. Ensure that it is always shielded by the phantom. 1100 Al alloy or acrylic are acceptable for phantom construction.

(8) Use a phantom to chamber distance of approximately 8 cm. This distance allows for adequate shielding of medium and larger image intensifiers. Very large IIs may require that the phantom be placed closer to the ion chamber.

(9) Place the grid in the beam path.

(10) Collimate the field to the phantom.

(11) Maintain consistent phantom/ ion chamber/image intensifier positions to assure reproducibility (record distances).

(12) Equipment arrangement modifications are not required for cine EER measurements unless specified by the equipment manufacturer.

d. Measurement Considerations:

(1) Refer to Tables D-1, D-2, & D-3.

(2) Make EER measurements using all available output rate and II size combinations. Include manual and pulse modes, if available. ABC systems will demonstrate different output rates at each II size to compensate for the loss of minification gain.

(3) For manual mode readings, adjust kVp and mA to provide a monitor image brightness equal to that of ABC normal mode.

(4) Make EER measurements with and without the grid in place, as warranted. The grid generally remains in the beam but may be removed if no-grid studies are performed.

(5) Use minimal "beam - on" time to prevent unnecessary x-ray tube wear. A properly functioning detector should settle down to a constant reading within 10 seconds.

(6) Correct raw measurements for temperature, pressure and energy dependence.

(7) Treat LUA systems as standard fluoroscopic systems with minimum source to chamber distances and chamber to II distances of 30 cm. Calculate table transmission factors for maximum kVp and the kVp set by ABC for the phantom. Add table transmission factors to the correction factor list.

(8) If the unit is equipped with high level control (HLC), a distinct tone must be heard when HLC is active.

(9) Some detector systems may not provide accurate EER measurements in pulse mode due to an inability to evaluate sub-second radiation pulses. Some sophisticated systems can be programmed to measure pulse fluoro. For less advanced systems, calculate a mean exposure rate from a single integrated reading of at least 10 seconds at a known pulse rate. During acceptance, evaluate multiple pulse rate settings. During annual evaluations, test the most commonly used pulse rate.

e. Cine Output Measurements:

(1) As most cine systems work at 30 and 60 frs^{-1}, cine EER measurements may suffer from problems similar to those in pulse fluoro.

(2) Bypass the cine camera safety interlock that prevents the unit from working when unloaded unless film frame numbers are to be counted in conjunction with an integrated exposure measurement.

(3) Measure EER using the most commonly used II size and ABC or manual techniques suitable for an average patient (i.e. 4 cm aluminum phantom). Evaluate all available image intensifier sizes during acceptance.

(4) Consider using one of the following measurement techniques:

(a) Program the test frame rate into the detector system (for advanced systems).

(b) Obtain a current mode reading and divide it by the frame rate.

(c) Obtain an integrated output reading for a 10 to 15 second run while actually exposing cine film. Calculate the mean exposure rate using the exposed frame count.

f. Interpretation of Results: Typical EER values should be significantly lower than their maximum output rate counterparts. Use acceptance inspection values to set baselines for future reference. Subsequent annual evaluation results should agree reasonably well with original levels (e.g. ± 10 %).

3. ***Maximum Entrance Exposure Rate***

a. Purpose: To prevent excessive exposure to patients subjected to fluoroscopic examinations by verifying that the maximum EER conforms to the limits of 21 CFR.

b. Regulations: 21 CFR Parts 1020.32.(d) and (e) specify maximum exposure rates allowed for fluoroscopic equipment manufactured prior to and after 19 May 1995, respectively. Table D-1 provides a summary of the appropriate limits. Table D-2 indicates the required ion chamber measurement locations based on equipment type.

c. Equipment: 4 cm Al or 15 cm acrylic phantom, 1.6 mm Pb plate, exposure meter with small ion chamber.

d. Procedure:

(1) Set up the fluoro unit, phantom, and ion chamber as for typical EER measurements. Sections A.2.c.(1) to (11) apply.

(2) Place the lead sheet on top of the phantom between the ion chamber and image intensifier.

(3) Make EER measurements in the same manner as outlined in section A.2.d. for all available output modes. For manual modes, set kVp to its maximum level.

(4) Maximum EER measurements need only be made at the largest II size.

(5) Radiation streaming around the lead plate should not be visible during testing.

(6) Warning: Image intensifiers may be irreparably damaged if exposed to unattenuated high energy x-ray beams for extended periods.

e. Interpretation of Results: Ensure that proper ion chamber/lead/II distances are maintained. Maximum EER measurements may be unduly influenced (10 to 15 % above equivalent free in air measurements) by backscatter from the lead sheet if the ion chamber is too close to the phantom/lead assembly. If maximum exposure rates exceed limits set in Table D-1, recommend that the unit be temporarily removed from patient use and recalibrated by a qualified service engineer as soon as possible. If practicable, verify that the new maximum exposure rates are acceptable before the service engineer leaves the facility.

4. ***Leakage Through Primary Barrier***

a. Purpose: To verify that the radiation attenuation provided by the II housing is adequate.

b. Equipment: 4 cm Al phantom, 1.6 mm Pb plate, exposure meter with large ion chamber.

c. Procedure:

(1) Arrange the fluoro unit, phantom, and Pb sheet in the same manner as for evaluating maximum EER. Section A.3.(d) applies.

(2) Place the large ion chamber 10 cm beyond the rear surface of the primary barrier (i.e. II housing) with the large flat surface perpendicular to the beam axis.

(3) Irradiate the phantom using the maximum EER technique. Record the radiation level and compare it with the maximum EER recorded previously.

d. Interpretation of Results: Radiation levels at 10 cm beyond the II housing should not exceed 1 $mRhr^{-1}$ for each $Rmin^{-1}$ measured in Section A.3.. Refer units showing excessive radiation transmission for repair by a qualified service engineer.

5. ***Beam Quality (Half Value Layer)***

a. Purpose: To verify that the permanently installed filtration in the tube housing is thick enough to minimize patient exposure.

b. Regulations: 21 CFR Part 1020.30(m) specifies the minimum beam quality (HVL) requirements for a range of tube potentials.

c. Equipment: 1100 aluminum alloy HVL sheets, exposure meter with small ion chamber, test stand, 4 cm aluminum phantom.

d. Procedure:

(1) Arrange the unit for largest available II size, grid in the beam, collimator fully open, and an SID that allows insertion of the test stand between the II and tube.

(2) Using the test stand, place the small

ion chamber in the center of the fluoro field, approximately midway between the tube and II.

(3) If the unit allows manual kVp and mA control, use the following procedure:

(a) Manually set kVp = 90.

(b) Place the 4 cm aluminum phantom between the ion chamber and II. Allow some separation between the two to minimize the effect of backscatter.

(c) Under fluoro, collimate the beam to an area just larger than the ion chamber. **Ensure that the phantom always intercepts the beam. Failure to do so may damage the II.**

(d) Set mA to produce an output rate between 300 and 500 mR/min.

(e) Measure the exposure rate without any Al sheets between the tube and ion chamber. Repeat the measurement with 1, 2, 3, 4, and 5 mm Al between the tube and ion chamber.

(4) If the unit does not permit manual technique control (i.e. ABC only), use the following procedure:

(a) Place the Al phantom and collimate the beam per steps 5.d.(3)(b) and (c).

(b) Place all 5 mm Al sheets between the ion chamber and II (e.g. above the Al phantom).

(c) Measure the exposure rate without any Al sheets between the tube and ion chamber, allowing ABC to set kVp for all the aluminum in the beam (i.e. phantom + sheets).

(d) Repeat the measurement with 1 through 5 mm Al between the tube and ion chamber; moving each Al sheet from behind the ion chamber to in front of it. **A constant Al thickness must remain in the beam throughout the procedure to prevent ABC from changing technique factors. Varying factors will lead to erroneous readings.**

(5) Determine HVL for the appropriate voltage potential (set manually or obtained through ABC) mathematically using logarithmic interpolation or graphically using semi-log paper.

e. Interpretation of Results: Table B-1 lists minimum HVLs for various voltage potentials. If the beam does not meet the minimum standard, refer the unit for adjustment by a qualified service engineer. Insufficient filtration may lead to unnecessary patient dose. A unit with a hard beam need not be removed from service. However, a high HVL often indicates the presence of an older tube that may fail shortly thereafter.

6. ***Minimum Source to Skin Distance (SSD)***

a. Purpose: To prevent unnecessary patient exposure resulting from an unduly short source to skin distance (SSD).

b. Regulations: 21 CFR Part 1020.32(g) specifies the minimum source to skin distance requirements based on fluoroscopy unit mobility and application.

c. Equipment: Tape measure, etched brass plate, 14" x 17" (35 cm x 43 cm) loaded cassette.

d. Procedure:

(1) For C-arm systems, determine minimum SSD using a tape measure. Measure from the external target position mark to the end of the collimator assembly or spacing cone if permanently installed. Treat LUA systems in the same manner.

(2) For fixed SID, overhead tube systems, measure minimum SSD in the same manner as step (1).

(3) For fixed SSD, undertable tube systems that allow tube access, measure minimum SSD using a tape measure as the distance from the target mark to the tabletop. For systems with variable SSD, set the target to table distance to minimum before measuring.

(4) For fixed SSD, undertable systems without tube access, measure minimum SSD using triangulation as described on page 4 - 1, reference 4. Calculate SSD as:

$$SSD = \frac{OID}{(w_2/w_1) - 1}$$

Where OID = Brass plate to film image distance

w_2 = Division length at SID
w_1 = Division length on the plate

e. Interpretation of Results: If the source to skin distance is less than required, refer the unit for adjustment by a qualified service engineer.

7. ***Minimum and Maximum Fluoroscopic Image Size (Beam Limitation Devices)***

a. Purpose:

(1) To verify that the fluoroscopic imaging system displays the geometrically appropriate anatomical area of interest.

(2) To prevent unnecessary patient exposure due to irradiating anatomic areas larger than the image receptor.

b. Regulations: 21 CFR Part 1020.32(b) specifies that the minimum radiation field size at maximum SID shall be contained within a square of 5 cm by 5 cm.

c. Equipment: Etched brass plate, 14" x 17" (35 cm x 43 cm) loaded cassette.

d. Procedure:

(1) Arrange the unit for maximum SID, largest available II size, grid in the beam, and all collimators fully open.

(2) Position the brass plate between the tube and image intensifier to fully intercept the beam.

(3) Using appropriate protection, place the cassette as close to the II face as possible with the screen facing the tube. Center the cassette over the II housing assembly.

(4) Expose the cassette for 1 - 2 sec using a low technique (50-60 kVp @ 1 mA).

(5) Close all collimators completely.

(6) Move the cassette over to align the center of the image intensifier with a corner of the cassette.

(7) Re-expose the cassette per step (4).

(8) Measure the dimensions of the darkened areas on the processed film. Correct the measurements if a significant cassette to II distance existed during exposure.

e. Interpretation of Results: If the maximum or minimum field size dimensions exceed tolerance limits, recommend that a qualified service engineer recalibrate the collimators. One method to eliminate the film based beam limitation test procedure is to calibrate the collimator shutters so that they are just visible along the edges of the live image at maximum field size. Once the collimators are properly calibrated, maximum field size conformance can be verified visually on the monitor image.

8. ***Fluoro Display Field Alignment***

a. Purpose: To verify that the fluoroscopy beam is properly collimated so that only the tissue volume corresponding to the active entrance area of the II is irradiated, & that the same volume is presented on the monitor.

b. Equipment: Etched brass plate, plastic cylinder with stacked steel balls, 14" x 17" (35 cm x 43 cm) loaded cassette, 2-D level.

c. Procedure:

(1) Arrange the system for minimum SID, largest available II size, grid in the beam, and collimators fully open.

(2) Position the brass plate to obtain an object to image distance (OID) of approx. 30 cm and collimate the image as necessary so that the plate fully intercepts the beam. Place the plastic cylinder on top of the plate, superimposing the plate center and lower steel ball. Using the level, ensure that the horizontal tool surfaces are perpendicular to the beam axis.

(3) Under fluoro, position the plate so that the two steel balls are superimposed in the monitor image.

(4) Using appropriate protection, place the cassette as close to the II face as possible with the screen facing the tube. Center the cassette over the II

housing assembly.

(5) Expose the cassette using normal fluoro to acquire a background film density of approximately 1.2 (≈ 1 sec at 80 kVp and 200 mA). Process the film.

(6) On both the monitor and film images, determine the indicated distance between opposing edges of the viewing field (TV) or radiation field (film) along the two axes on the plate.

(7) Compare the axis lengths in the monitor and film images and calculate the difference between the two as a fraction of SID.

(8) If the unit allows, increase SID to maximum and repeat steps (6) and (7) during acceptance testing. In a properly functioning unit, collimation should track automatically with changing SID.

d. Interpretation of Results: If the difference between the lengths of either monitor/film axis pair exceeds 3 % of SID or if the sum of the differences for both axis pairs exceeds 4 % of SID, refer the system for recalibration by a qualified service engineer.

9. ***Beam Central Alignment***

a. Purpose: To verify that the fluoroscopy beam central axis is properly aligned with the center of the image intensifier.

b. Equipment: Etched brass plate, plastic cylinder with stacked steel balls, 2-D level.

c. Procedure:

(1) Complete steps (1) through (3) of the fluoro display field alignment procedure.

(2) If the fluoroscopy beam and II are properly aligned, the two balls will be superimposed and all four axis arms will have equal length. Absence of these two conditions indicates imperfect alignment.

(3) Reposition the plate to provide four equal axis arm lengths. On the monitor image, locate the position of the upper steel ball relative to the pair of etched concentric circles indicating central axis deviations of 1.5 and 3 degrees from the perpendicular.

d. Interpretation of Results: If the beam axis/II misalignment exceeds 1.5 degrees, refer the system for imaging chain repositioning by a qualified service engineer.

10. ***Pincushion and "S-ing' Distortion***

a. Purpose: To verify that the fluoroscopic image contains minimal spatial distortion and artifacts.

(1) It is difficult to quantify an amount of acceptable distortion. However, any distortion should be horizontally and vertically symmetrical. It should also be visibly similar for fluoroscopic, cine, and digital spot images produced using the same II.

(2) Two major forms of spatial distortion are pincushion distortion and S-ing. Pincushion is characterized by bowing of peripheral chords into the center of the image. S-ing is characterized by warping of straight lines passing through the center of the image into "S" shapes in the central quarter to third of the image.

b. Equipment: Etched brass plate

c. Procedure:

(1) Verify that the unit meets the standards for fluoro display field and beam central alignment.

(2) Proceed from step (3) of the fluoro display field alignment procedure, Section 8.c.

(3) Remove the plastic cylinder from atop the brass plate. Recollimate the field, if necessary, so that the etched lines forming the axes and rectangular outline are clearly visible in the monitor image.

(4) Observe the image, paying special attention to the effects of excessive spatial distortion.

(5) For adjustable units, move the imaging chain through its full SID range noting changes in the level of distortion with changing SID.

e. Interpretation of Results: If the amounts of pincushion distortion or S-ing exceed the levels prescribed in Table 4.1, refer the system for adjustment by a qualified service engineer. Due to

the subjectivity of this test, last hold hard copy reference images showing the level of distortion during acceptance may be invaluable during subsequent periodic testing.

11. ***High Contrast Resolution***

a. Purpose: To verify the system's ability to resolve high contrast objects under variable operating conditions and using multiple recording modes.

b. Equipment: High resolution test patterns, 1 mm sheet of 1100 aluminum alloy.

c. Procedure:

(1) Arrange the unit for maximum SID, largest available II size, grid & compression cone out of the beam, and all collimators open.

(2) Attach the test pattern as close to the II face as possible. Place the aluminum sheet between the tube and test pattern so as to fully intercept the beam and collimate the beam to the periphery of the test pattern.

(3) If the unit allows manual kVp and mA control, set kVp = 60 and adjust mA for image brightness that provides the best viewing. If the unit uses ABC, use the kVp and mA provided by the unit for 1 mm Al and test pattern in the beam.

(4) Determine the highest density mesh visible at the image center and periphery. A resolvable mesh should clearly show bright wires separated by dark spaces and be free of Moiré patterns. Due to variable electronic focusing across the II, resolution is typically better in the field center than at the periphery.

(5) Repeat the measurements using all available output rate and II size combinations. Include manual and pulse fluoro, cine, and spot filming (mechanical & digital) during acceptance testing to set image quality baselines for future reference. During periodic testing, evaluate a representative subset of the acceptance group. Table 4 - 1, Number 11 refers.

(6) Make hard copy record images of the test pattern for those modes that allow filming.

d. Interpretation of Results: Table D-4 lists expected high contrast mesh values for image intensified fluoroscopy systems. Individual manufacturers may set more rigorous standards. High contrast resolution for ancillary imaging modes should equal that of their normal dose rate, live fluoro counterparts at the same II size. If the observed resolution does not meet the appropriate standard, recommend that the unit be serviced by a qualified service engineer.

12. ***Low Contrast Sensitivity***

a. Purpose: To verify the system's ability to display low contrast information.

b. Equipment: 4 cm Al phantom, multi-perforated Al sheet.

c. Procedure:

(1) Arrange the fluoroscopy unit in the same manner as for making EER measurements, with largest available II size and grid in the beam. Sections A.2.c.(1), (4), and (5) apply.

(2) Place the perforated sheet between the two larger pieces. For units with attached tables, place the combination phantom on the tabletop. For C-arms, place the combination phantom at the same location as for EER measurements.

(3) Collimate the field to the periphery of the phantom, ensuring that all sets of holes are within the image.

(4) If the unit allows for manual kVp and mA control, set kVp to between 85 - 90 and adjust mA for image brightness that provides best viewing. During contrast sensitivity viewing, ensure that enough tube current is applied to prevent the brightness difference from being lost in the image noise. If the unit uses ABC, use the kVp and mA provided by the system for the combination phantom in the beam.

(5) Determine the smallest pair of targets visible with the unaided eye. To count a given target, both circles should be clearly visible against the phantom background.

(6) Repeat the measurement using all

available output rate and II size combinations. Include manual and pulse fluoro, cine, and spot filming (mechanical and digital) during acceptance testing to set image quality baselines for future reference. During periodic testing, evaluate a representative subset of the acceptance group. Table 4 - 1, Number 12 refers.

(7) Make hard copy record images of the visible hole pattern for those modes that allow filming.

d. Interpretation of Results: Image intensified fluoroscopy systems should resolve at least a 3.1 mm diameter object at 2 % nominal subject contrast. Pulse fluoro images may be formed with subsecond photon bursts, making them difficult to assess visually. Low pulse rate images should not be held to the same standards as their continuous beam counterparts. Low contrast sensitivity for cine and mechanical spot film images should equal that of their normal dose rate, live fluoro counterparts at the same II size. If the observed sensitivity does not meet the baseline set at acceptance, refer the unit for adjustment by a qualified service engineer.

13. ***Mechanical Spot Film Automatic Exposure Control (AEC)***

a. Introduction:

(1) Automatic exposure control systems attached to fluoroscopy spot film devices provide the same function as their radiographic system counterparts; i.e. compensation for variations in technique factors and patient thickness such that resulting spot films appear with constant, optimal densities.

(2) This evaluation assumes proper operation of the processor used to develop spot films. It also assumes that the AEC system is calibrated for the film/screen combination used with the unit. Therefore, the processor, cassette, and film used for testing should be those actually used during patient imaging. Also, test films should all come from the same emulsion batch.

(3) The following AEC parameters should be evaluated during testing: reproducibility, maximum exposure time, kVp compensation, patient thickness compensation, density control function, and multi - image format (field size) compensation.

b. Equipment: 4 cm Al or 18 cm acrylic phantom, 1.6 mm Pb plate, 14" x 17" (35 cm x 43 cm) loaded cassette, exposure meter with small ion chamber.

c. Procedure:

(1) Arrange the unit in the same configuration used for measuring fluoroscopic EER. Section A.2.c. applies. Ensure that if a grid is used clinically, it is in the beam path during testing.

(2) Record the SID, film/screen combination, and film size used for future testing reproducibility.

(3) Place the loaded cassette in the tower. Program the spot film device for 1:1 image format and move the cassette to the ready position.

(4) Place a 4 cm aluminum or 15 cm acrylic phantom in the beam in the same manner as for measuring EER. Ensure that the phantom covers all the AEC detector cells.

(5) Set the II field to its largest setting, collimating to the phantom periphery if necessary. Fluoro the phantom briefly, allowing the ABC to select an appropriate kVp. Several systems apply the ABC selected kVp directly to the mechanical spot film technique. For those that do not, the fluoro kVp serves as a useful guideline for manual spot film technique programming. For units without ABC, use 80 kVp.

(6) Program the spot filmer as follows: manual kVp and mA selection, exposure time determined by AEC. If more than one detector cell is available and cells can be programmed to work independently, select the center cell, otherwise use all cells simultaneously.

(7) Use a single cassette for testing. This will require processing the film after each exposure.

(8) Measure and record the OD at the center of the field. The OD should be at least 1.2. The radiologist may set a higher baseline density. The range of densities should be within ± 0.15 of the baseline density.

d. *Output Reproducibility:*

(1) Use the basic imaging chain arrangement and phantom thickness. Place the ion chamber along the beam central axis at the phantom beam entrance surface. Set technique factors as follows: kVp from the fluoro image or, in the absence of ABC, 80 kVp; 200 mA, AEC setting to neutral (0). Substitute an exposed piece of film for fresh film during this test.

(2) Irradiate the phantom, ion chamber and cassette holding exposed film three times. Record the exposure readings and calculate their mean.

(3) All three readings should lie within ± 5% of their mean.

e. *Maximum Exposure Time*:

(1) Use the basic imaging chain arrangement and phantom thickness. Place the lead sheet over the AEC detector fields so that no radiation reaches them. Set technique factors as follows: kVp from the fluoro image or, in the absence of ABC, 80 kVp; 200 mA, AEC setting to neutral (0). Retain the previously exposed film from the reproducibility test.

(2) Irradiate the phantom until AEC shuts off the beam. Record the elapsed mAs.

(3) The beam should terminate prior to the accumulation of 600 mAs.

(4) Replace the exposed film with a fresh piece at the end of the procedure.

f. *kVp Compensation*:

(1) Use the basic imaging chain arrangement and phantom thickness. Set technique factors as follows: 200 mA, AEC setting to neutral (0).

(2) Vary kVp over the clinically used range 70, 80, 90, 100, and 110 kVp, irradiating a separate film for each voltage potential. Record the elapsed mAs for each image and measure the optical density at the center of each processed film using a densitometer.

(3) The densities should lie within the range of ± 0.3 of the baseline density.

g. *Patient Thickness Compensation*:

(1) Use the basic imaging chain arrangement. Set technique factors as follows: kVp from the fluoro image or, in the absence of ABC, 80 kVp; 200 mA, AEC setting too neutral.

(2) Vary phantom thickness over the range: 2, 4 cm Al or 12, 15, and 18 cm acrylic, irradiating a separate film for each phantom thickness. Record the elapsed mAs for each image and measure optical density at the center of each processed film using a densitometer.

(3) The densities should lie within the range of ± 0.3 of the baseline density.

h. *Multi-image Format (Field Size Compensation)*:

(1) Use the basic imaging chain arrangement and phantom thickness. Set technique factors as follows: kVp from the fluoro image, or in the absence of ABC, 80 kVp, 200 mA, AEC to neutral setting (0). Set the imaging format to 4:1.

(2) Irradiate the phantom four times using the 4:1 film format. Record the elapsed mAs for each image and measure the optical density at the center of each darkened field using a densitometer.

(3) The four darkened images should occupy distinct areas on the film with no overlap. The densities should all lie within the range of ± 0.1 of

the baseline density.

i. *Density Control Tracking*:

(1) Use the basic imaging chain arrangement and phantom thickness. Place the ion chamber just off the beam central axis at the phantom beam entrance surface. Set technique factors as follows: kVp from the fluoro image or, in the absence of ABC, 80 kVp; 200 mA.

(2) Vary AEC density over the range of available positive and negative settings, exposing a new piece of film for each setting. Record the elapsed mAs, density at the center of each film, and exposure for each image.

(3) The density function should operate as expected; + gives exposure and density increase, - gives exposure and density decrease. The exposure difference per step should meet the manufacturer's specifications or in the absence of such data, be balanced about the neutral setting output at 25 % per step.

j. Interpretation of Results: Units deviating from the criteria in Table 4.1 should be referred for adjustment by a qualified service engineer. Spot films can constitute a significant fraction of the total radiation output during fluoroscopy procedures. Unfortunately, spot film AEC performance is frequently omitted in periodic testing following acceptance. Proper operation of the spot film device is essential as it frequently provides the only permanent record of the fluoroscopic procedure.

14. ***Mechanical Spot Film Alignment***

a. Purpose: To verify the alignment of the x-ray beam with the mechanical spot device.

b. Equipment: 4 cm Al or 18 cm acrylic phantom, 14" x 17" (35 cm x 43 cm) loaded cassette.

c. Procedure:

(1) Arrange the fluoroscopy unit in the same manner as for evaluating mechanical spot film AEC variation with changing field size. Section A.13.(h) applies.

(2) Open the collimators to maximum field size.

(3) Irradiate the phantom using all format sizes not tested during the AEC evaluation. Record each on a separate film. It may be necessary to use more than one cassette size to acquire all possible spot film formats.

d. Interpretation of Results: The resulting darkened fields should occupy distinct areas on the film with no overlap or shadowing among adjacent spot images. Refer spot film units showing adjacent image interference for recalibration by a qualified service engineer.

15. ***Entrance Skin Exposures (ESE) (Mechanical and Digital Spot Films)***

Refer to Appendix I for mechanical and digital spot film ESE measurement procedures. Tolerances for both formats are listed in Table 4.1.

B. Additional Performance Tests for Digital Fluoroscopic Equipment

1. ***Contrast Response***

a. Purpose: To verify the long term stability of the digital fluoroscopy system's programmed contrast response function.

b. Equipment: 10+ step Al wedge, densitometer

c. Procedure:

(1) Arrange the fluoroscopy unit in the same manner as for evaluating Fluoro Display Field Alignment. Section A.8.(c) applies.

(2) Position the wedge to obtain an object to image distance of approximately 30 cm and collimate the largest II field beam to the wedge periphery so that the test object fully intercepts the beam.

(3) Irradiate the wedge using the default technique factors provided by ABC. Record the image digitally using the last image hold feature.

(4) Record a second image of the wedge using the digital spot film feature and kVp provided by ABC.

(5) Print both images on a common sheet of laser film using 2:1 format. Measure the optical density of each image step. Plot density as a function of wedge thickness for both images.

d. Interpretation of Results: The acceptance curves should resemble the manufacturer's recommended defaults. Some variation may be necessary to accommodate radiologists' preferences. The original curves should be retained as baselines for future reference. Subsequent periodic evaluation curves should not differ significantly from their acceptance counterparts. Systems showing significant contrast response variations should be referred for further analysis and adjustment if necessary.